



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/470,603	12/22/99	DOVA	03743

HM42/0511

PETER J MANSO
AKERMAN SENTERFITT & EIDSON P A
LAS OLAS CENTRE II SUITE 1600
350 EAST LAS OLAS BLVD
FT LAUDERDALE FL 33301

JOYCE EXAMINER

ART UNIT 315

PAPER NUMBER

05/11/01

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/470,603 12/22/99 BOVA

D 20720-103793

HM22/1003

PETER J MANSO
AKERMAN SENTERFITT & EIDSON PA
LAS OLAS CENTRE II SUITE 1600
350 EAST LAS OLAS BLVD
FT LAUDERDALE FL 33301

EXAMINER

JOYNES, R

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

10/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/470,603

Applicant(s)

BOVA, DAVE

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment dated December 22, 1999.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is confusing because the terms regarding liver damage are relevant. One of ordinary skill in the art may not recognize damage to the liver that is not serious. It is the position of the examiner that all damage to the liver is serious. It is suggested that the terms "little or no serious" (Claim 3, page 30, lines 11-12) before the word 'liver' be replaced with the term "minimum."

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is indefinite as it is improperly drawn to itself and does not dependent on a previous claim. It is suggested that Claim 11 be properly drawn to Claim 10. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1615

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Evenstad et al. (US 5126145). Evenstad et al. teaches a controlled release tablet containing a water-soluble medicament (Col. 1, lines 7-11).

The tablet may comprise about 5-30 percent by weight hydroxypropyl methylcellulose with sustaining properties (Col. 3, lines 18-20). The water-soluble medicament may comprise 50-85 percent by weight niacin or nicotinic acid (Col. 2, lines 40-47). The tablet may also comprise 2-8 percent by weight of a pharmaceutical binder such as polyvinyl pyrrolidone (Col. 3, lines 45-51) as well as 0.5-5 percent by weight of an external lubricant such stearic acid or magnesium stearate (Col.5, lines 18).

The release rate of the tablet is such that 10-35% is released in 2 hours, 40-70% is released in 8 hours and at least 90% is released in 24 hours (Col. 5, lines 66-68 – Col. 6, lines 1-5). The sustained release tablet can also aid in the avoidance of undesirable side effects (Col. 1, lines 46-47).

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Neill et al. (US 5268181) O'Neill et al. teaches a method of using a sustained release tablet containing niacin or nicotinic acid to treat nocturnal cholesterol synthesis (Col. 2, lines 36-53).

The tablet may comprise about 5-30 percent by weight hydroxypropyl methylcellulose with sustaining properties (Col. 4, lines 3-10). Niacin or nicotinic acid

Art Unit: 1615

may comprise 30-90 percent by total weight of the tablet (Col. 4, lines 3-10). The tablet may also comprise 2-15 percent by weight of a pharmaceutical binder such as polyvinyl pyrrolidone (Col. 4, lines 11-21) as well as 0.1-5 percent by weight of an external lubricant such as magnesium stearate (Col. 5, lines 24-31). The release rate of the tablet is such that 10-35% is released in 2 hours and 40-70% is released in 8 hours (Col. 4, lines 67-68 – Col. 5, lines 1-2). The sustained release tablet can also aid in the avoidance of undesirable side effects such as liver damage (Col. 3, lines 3-10).

O'Neill et al. also teaches that efficacy of the tablet is maximized during the night because triglyceride and cholesterol synthesis are predominantly nocturnal events (Col. 3, lines 53-60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evenstad et al. in view of O'Neill et al. The teachings of Evenstad et al. are summarized above. Evenstad et al. does not teach a method of treating hyperlipidemia by which a tablet is taken at night.

O'Neill et al. teaches the method of administering a sustained release tablet comprising niacin in a single dose in the evening or prior to sleep. The teachings of O'Neill et al. are summarized above.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to maximize the effect of drugs in relationship to the metabolism of the body. It is the position of the examiner that prior art has obtained this result i.e., the reduction of low-density lipoprotein (LDL), and that no criticality is seen in applicant's particular nocturnal method of administering the sustained release tablet comprising niacin. Any distinction is a matter of degree and not of kind. Therefore, it is the opinion of the examiner that the invention is deemed to obvious to one of ordinary skill in the art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISOR, PATENT EXAMINER
TECHNOLOGY CENTER 1600